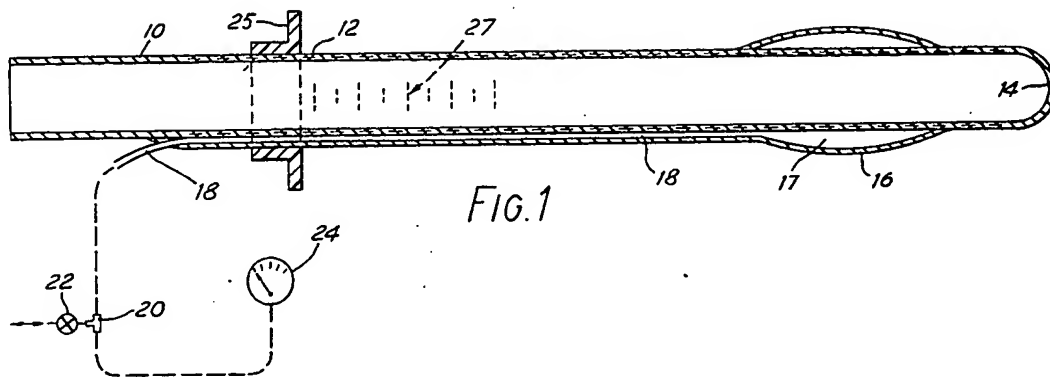


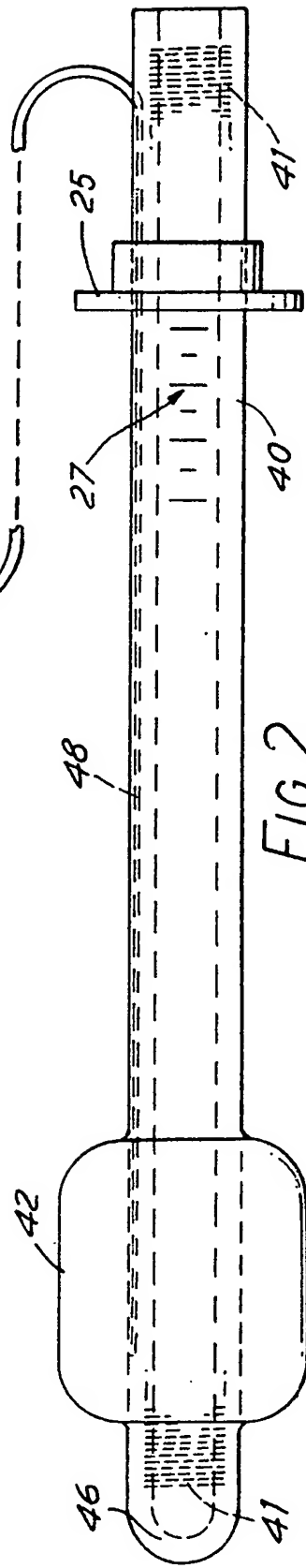
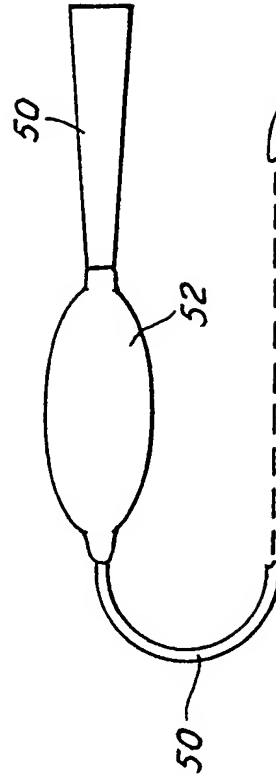
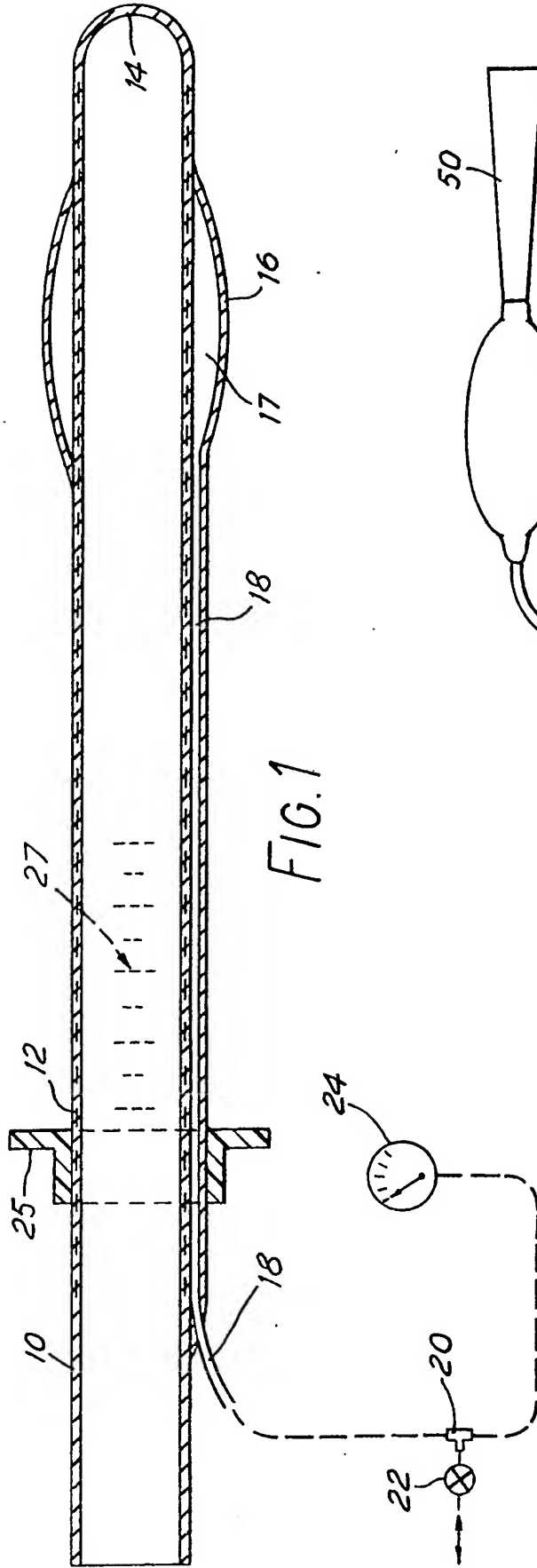
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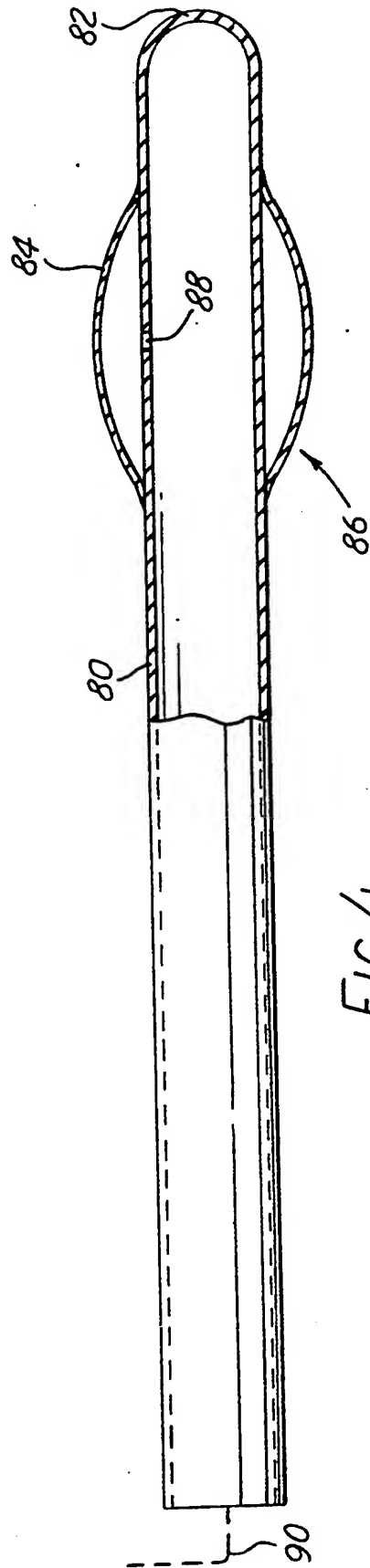
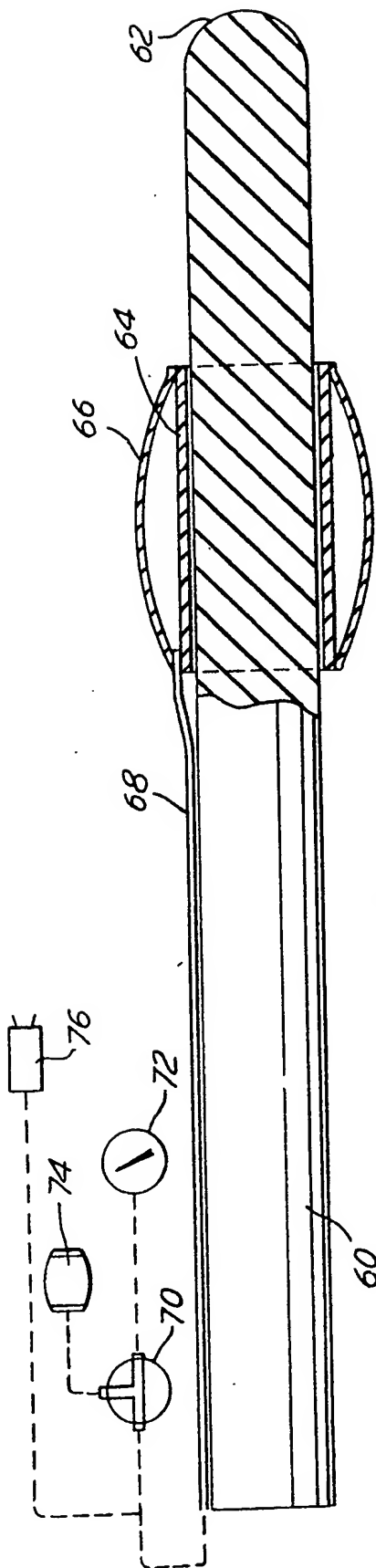
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(54) Device for developing control of
sphincter-type muscles

(57) A device is proposed for assisting a person to exercise and improve his or her control of sphincter-type muscles. It has a cylindrical elongated support member 10 which carries or in part defines an inflatable cuff 16 having a longitudinal extent which is less than one quarter of that of the member. There are means 18 for transmitting changes in pressure in a fluid within the cuff to a display device 24 separate from the member.







SPECIFICATION

A device for developing control of sphincter-type muscles

5 This invention relates to a device for assisting a person to exercise and strengthen and improve his or her control of certain internal muscles herein called sphincter-type muscles.

10 In this specification, the term "sphincter-type muscle" is used to mean any internal muscle in the human body which plays a part in controlling the excretory functions. Examples are the anal sphincter muscle and the levatores ani group of muscles of the

15 pelvic floor, in particular the pubococcygeus muscle. It has been suggested that the muscles around the urethral-vagina area in women can be stimulated electrically, so causing the muscles to contract and control discharge of urine. Devices with small electrodes have been proposed but are in general
20 expensive and not popular with users. An example of this kind of device is shown in U.S. Patent Specification 3 640 284 of DE LANGIS.

The present invention is based on a different
25 approach, namely assisting the patient to develop a mental control over the relevant muscles. A patient who is trying to develop this control must have a clear feedback of his or her success or failure, and to the best of the Applicants present knowledge and belief, no fully satisfactory device for giving such a
30 feedback exists. KEGEL in U.S. Patent Specifications 2 507 858 and 2 541 520 suggests methods and a device for indicating or observing the exercising of injured sphincter muscles. The device has a core and
35 a laterally-extending vulcanised rubber disc which forms a stop to limit the extent of insertion. A flexible and expansible bulb surrounds the core. In use the device is inserted up to the stop and the bulb is inflated to bring its wall into engagement with the
40 wall of the muscle of interest. A pressure gauge connected to the interior of the bulb is then used to monitor compression of the bulb achieved by the efforts of the user in intentionally contracting the muscle of interest. This device has achieved a certain
45 amount of practical use but is not popular among users because it is uncomfortable to insert and to use and the results obtained often are not sufficiently specific to a particular muscle of interest. Developments of this general concept are disclosed in U.S.
50 Patent Specifications 3 502 328 (HAMILTON), 3 726 273 (COLE) 3 752 150 (HARRIS), 3 926 178 (FELDZAMEN), 4 048 985 (SASSE), 4 050 449 (CASTELLANA ET AL), 4 167 938 (REMIH), 4 216 783 (KAISER ET AL), and British Patent Specification
55 1 319 228 (BUNING).

Certain conflicting requirements desirably should be met in a device of this kind which is intended for home use by relatively unskilled and non-medical persons. Firstly, the device must be stiff enough to
60 insert to the required distance, without it collapsing; secondly, the device must be of a shape and surface texture that is easily and comfortably inserted; and thirdly, it must be sensitive enough to clearly register muscle movements on a display unit such as
65 a pressure gauge even though only a *very slight*

muscle movement may have taken place.

According to the present invention, a device for assisting a person to exercise and improve his or her control of sphincter-type muscles comprises a substantially cylindrical elongated support member
70 which carries or in part defines an inflatable cuff having a longitudinal extent which is less than one quarter of that of the member, a flange serving as a location device carried by and optionally adjustable along the member, and means for transmitting
75 changes in pressure in a fluid within the cuff to a display device separate from the member.

The elongated member may be marked with markings or graduations so that the flange position
80 can be noted when the device is first inserted, for example by a medical practitioner, who will be able to locate the cuff properly in relation to the particular muscle whose tone is to be evaluated or improved. In general the flange will be placed in contact with
85 the external surfaces of the labia majora and the member adjusted to correctly locate the cuff relative to the muscle. The user is then able to use the device without the presence of the medical practitioner, having noted the flange position, secure in the
90 knowledge that the muscle of interest and not an adjacent muscle is being monitored and exercised.

In one embodiment of the invention, the cuff is inflated with a gas, preferably air, and the device includes a conduit for the gas for inflating the cuff,
95 and a branch conduit connectible to a pressure gauge serving as the display device.

According to one embodiment of the invention, the support member may be a tube with one closed and one open end, made of latex rubber reinforced
100 over a major part of its length with fibre or cord. This reinforcement is to impart the required stiffness to the tube.

In a preferred version of the invention, the inflatable cuff is formed by an internal wall constituted by
105 part of the support member and an external wall which is freely stretchable and is of thin latex rubber. The said conduit may be formed by a second tube or by the hollow centre of the tube constituting the support member.

In an alternative embodiment of the invention, the inflatable cuff may be formed by a hollow annular member of substantially toroidal or "doughnut" shape, slidable along the length of the elongated support member. The interior of the cuff is then
110 connected to the conduit so that initially the cuff can be inflated and thereafter the changes in internal pressure therein produced by sphincter-type muscle movement can be monitored by a pressure gauge. By arranging that the cuff is of limited longitudinal
115 (i.e. axial) extent firstly it is possible to secure that a particular selected muscle is monitored, and secondly the sensitivity of the device is improved because slight muscle movements produce only a small change in the volume inside the cuff, and hence as
120 the total internal volume of the cuff is small, these small volume changes constitute a greater proportional change in the pressure reading on the gauge, than is the case with the prior art devices surveyed above.

130 According to a particular embodiment of the

invention, the device includes a tube forming a support member and having an inflatable cuff near one end, a second tube opening into the interior of the inflatable cuff, a pressure gauge attached to the other end of the second tube, and a valve whereby air or gas can be allowed to enter the second tube in order to inflate the cuff.

Also accordingly to this embodiment of the invention there is provided a device for assisting a female to control incontinence comprising a first reinforced rubber latex tube having an inflatable cuff near a closed and rounded end thereof and means for inflating the cuff and for connecting the interior of the cuff when inflated to a suitable pressure gauge. Such a first tube may be reinforced in any suitable way to give it a degree of stiffness while not being rigid such that it can be inserted comfortably in the vagina, and its distal end may be closed and rounded. The tube is preferably made of latex rubber by a dipping process and may be amalgamated by said dipping process with a second and thinner latex tube which is connected to the interior of the cuff.

The invention will be better understood from the following non-limiting description of an example thereof given with reference to the accompanying drawings in which:-

Figure 1 illustrates one example of a device according to the invention,

Figure 2 illustrates a second example of a device in accordance with the invention,

Figure 3 illustrates a third example of a device according to the invention, and

Figure 4 illustrates a fourth example of a device according to the invention.

Referring to *Figure 1*, a rubber tube 10 has reinforcement 12 over most of its length, and has a rounded closed end 14. An inflatable cuff 16 is located near the end 14 and a second tube 18 is in communication with the interior 17 of the cuff. The tube 18 is connected to a T-piece 20 which is in turn connected to a valve 22 and a pressure gauge 24. The tube has a flange 25 slidable along it which enables the user to locate the device in the same position each time it is used. As an optional refinement, graduations 27 may be marked on the tube so that the user can note the position of the flange 25 when the cuff 16 is properly located relative to the muscle being exercised.

The method of use is as follows. The device is inserted into the vagina. The valve 22 is opened and the cuff inflated in any convenient way to a light pressure, for example 40 to 60 mm of mercury, whereupon the valve 22 is closed. The patient then with the encouragement of the nurse attempts to contract her vaginal muscles, and her resultant efforts show clearly on the pressure gauge.

Referring now to *Figure 2*, the illustrated device includes a first tube 40 of rubber latex formed by dipping, there being a nylon cord reinforcement 41 wound at 24 turns per 25 mm. tube length embedded in the tube wall; this is to prevent collapse of the tube 40 for example during insertion. A floppy cuff 42 has a thin rubber latex wall and may have an axial length of about 40 mm. This may be varied. The distal end of the cuff may be spaced about 20 mm.

from the closed distal end 46 of the tube 40. An inflation lumen 48 is provided in the tube 40 and this opens into the interior of the cuff near its distal end. The lumen 48 is directly connected to an external thin tube 50 incorporating a test balloon 52. This gives a visual indication to the user because it is distended when the cuff is inflated. The tube 50 leads to a valve and pressure gauge in the same way as in the *Figure 1* embodiment of the invention. Of course the pressure gauge may be mechanical, electrical or electronic. A muscular contraction will show as an increase in pressure of about 1-8 mm. of mercury on the gauge, and so will be clearly noticeable to the patient. The tube 40 may for example have an I.D. of 9 mm., an O.D. of 16 mm., and an overall length of 220 mm. The reinforcement may extend over the length of the tube except for about 10 mm. at the distal end. The lumen 48 may be formed by a continuation of the tube 50 made integral with the tube 40 by a latex dipping operation.

The tube 10 or 40 as the case may be can be made of other suitable materials, for example PVC or polyurethane with nylon or metal wire reinforcement.

In one embodiment of the invention, the pressure gauge 24 may be an electronic pressure sensor unit capable of giving either a numerical display of pressure value or a display of lights, for example of different colours, triggered by the achievement of certain pressure values. For example with such a unit it could be arranged, using suitable circuitry the techniques for which are well known in the electronic arts, that a given muscle contraction (and hence a given pressure) illuminates a lamp of one colour, a greater contraction illuminates a lamp of a second colour, and a greater contraction still illuminates a lamp of a third colour. Such a unit would preferably include a means of controlling the sensitivity so that the particular levels of pressure at which given lamps are illuminated could be adjusted for example by a medical practitioner or a medical auxiliary.

The device illustrated in *Figure 3* has a substantially cylindrical solid rubber or plastics mandrel 60 with a rounded end 62. For example the mandrel may be about 6-8 inches in length and of a diameter of about 3/8 to 3/4 inch. The mandrel 60 carries slidably mounted thereon a sleeve 64 of rubber or plastics material, which in turn has fixed thereto in air-tight fashion a thin flexible and extensible latex rubber wall 66. The sleeve 64 and wall 66 together define an inflatable cuff to the interior of which is connected a thin-walled tube 68. The tube 68 may be suitably fastened to the mandrel 60, in such a way as to allow slidable movement of the cuff along the mandrel. The tube 68 is connected to a T-piece and valve 70 and thence alternatively to a pressure gauge 72 or a manually-operable inflator bulb 74. An advantage of this construction is that the inflatable cuff can readily be moved along the mandrel 60, nearer to or further from the end 62, as may be required to position it appropriately in relation to the muscle whose performance is to be monitored. A pressure relief valve 76 prevents a pressure greater than a predetermined limit being built up in the cuff 64, 66, even if the bulb 74 is continuously operated.

The device illustrated in Figure 4 has a hollow rubber latex tube 80 with a rounded end 82, its wall being of appropriate thickness or suitably reinforced (for example as described with reference to the device of Figures 1 and 2) to give the device a stiffness so that it can be readily inserted without discomfort and yet has sufficient rigidity not to be deformed by the muscle movements being monitored. The tube 80 has a thin flexible and expansible annular rubber latex wall 84, similar to the wall 16 of Figure 1, defining with the tube 80 an inflatable cuff 86. A hole 88 is provided in the wall of the tube 80 leading into the interior of the annular cuff 86. The interior of the tube 80 is connected by a line 90 to a T-piece and valve, bulb, pressure relief valve and gauge (all not shown) in the same way as illustrated in Figure 3.

Although not shown in Figures 3 and 4, a flange corresponding to the flange 25 in Figure 1, slidable along the tube, is preferably included in the arrangements shown in Figures 3 and 4.

For improved sensitivity, it is preferred to have a thin tube 18 (or 50, 48 or 68). For example it may have an I.D. of about 0.5 to 1.5 millimetres.

CLAIMS

1. A device for assisting a person to exercise and improve his or her control of sphincter-type muscles comprises a substantially cylindrical elongated support member which carries or in part defines an inflatable cuff having a longitudinal extent which is less than one quarter of that of the member, a flange serving as a location device carried by and optionally adjustable along the member, and means for transmitting changes in pressure in a fluid within the cuff to a display device separate from the member.

2. A device for assisting a female to control incontinence comprises a first tube having an inflatable cuff near one end, a second tube opening into the interior of the inflatable cuff, a pressure gauge attached to the other end of the second tube, and a valve whereby air or gas can be allowed to enter the second tube in order to inflate the cuff.

3. A device according to claim 1 or 2 in which the first tube is reinforced with a winding of a suitable reinforcing thread or wire over a major portion of its length.

4. A device according to claim 2 or 3 in which the first tube is amalgamated with the second tube by a latex dipping operation.

5. A device according to claim 1, 2 or 3 in which the distal end of the first tube is closed by a rounded end.

6. A device according to claim 3 in which the reinforcement is nylon cord wound at 24 turns per 25 millimetres of tube length.

7. A device according to claim 1 in which the inflatable cuff is formed by an internal wall constituted by part of the support member and an external wall which is freely stretchable and is of thin latex rubber.

8. A device according to claim 1, 6 or 7 in which the said conduit may be formed by a second tube or by the hollow centre of the tube constituting the

support member.

9. A device according to claim 1 in which the inflatable cuff may be formed by a hollow annular member or substantially toroidal or "doughnut" shape, slidable along the length of the elongated support member, and the interior of the cuff is connected to the conduit for initial inflation.

10. A device for assisting a female to control incontinence comprising a first reinforced rubber latex tube having an inflatable cuff near a closed and rounded end thereof and means for inflating the cuff and for connecting the interior of the cuff when inflated to a suitable pressure gauge.

11. A device according to claim 10 in which the tube is reinforced in any suitable way to give it a degree of stiffness while not being rigid such that it can be inserted comfortably in the vagina.

12. A device according to claim 10 or 11 in which the tube is preferably made of latex rubber by a dipping process.

13. A device according to claim 12 in which the tube is amalgamated by said dipping process with a second and thinner latex tube which is connected to the interior of the cuff.

14. A device for assisting a person to exercise sphincter-type muscles which includes a tube forming a support member and having an inflatable cuff near one end, a second tube opening into the interior of the inflatable cuff, a pressure gauge attached to the other end of the second tube, and a valve whereby air or gas can be allowed to enter the second tube in order to inflate the cuff.

15. A device for assisting a person to exercise and improve his or her control of sphincter-type muscles substantially as herein described with reference to and as illustrated in any one of Figures 1-4 of the accompanying drawings.